USSN 10/023,441
Art Unit: 1623

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of the Claims

1-98. (canceled)

99. (currently amended) A method of treating [a]at least one disease or disorder selected from the group consisting of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction, fatigue, lack of wakefulness, lack of appetite, and lack of weight gain, ~~in a mammal~~ comprising the step of orally administering to [the]a mammal a therapeutically effective amount of a modafinil compound:cyclodextrin mixture, wherein the mixture provides an aqueous solubility of the modafinil compound of at least about 30 mg/mL.

100. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture comprises an inclusion complex of a modafinil compound and a cyclodextrin.

101. (previously presented) The method of claim 99, wherein the modafinil compound is modafinil.

102. (previously presented) The method of claim 101, wherein the modafinil compound is the levorotatory form of modafinil.

103. (previously presented) The method of claim 99, wherein the cyclodextrin is selected from the group consisting of α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, dimethyl-β-cyclodextrin, trimethyl-β-cyclodextrin, 2-hydroxymethyl-β-cyclodextrin, 2-hydroxypropyl-β-cyclodextrin, 3-hydroxypropyl-β-cyclodextrin, β-cyclodextrin sulfate, β-cyclodextrin sulfonate, β-cyclodextrin sulfobutyl ether, and mixtures thereof.

104. (previously presented) The method of claim 99, wherein the cyclodextrin is a β-cyclodextrin.

105. (previously presented) The method of claim 104, wherein the cyclodextrin is selected from the group consisting of β-cyclodextrin, a hydroxypropyl-β-cyclodextrin and β-cyclodextrin sulfobutyl ether.

106. (previously presented) The method of claim 105, wherein the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin.

107. (previously presented) The method of claim 99, wherein the modafinil compound is modafinil and the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin.

108. (previously presented) The method of claim 107, wherein the modafinil compound is the levorotatory form of modafinil.

109. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture is in a solution form.

110. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture is in a solid form.

111. (canceled)

112. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 0.8:1 to 10:1.

113. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 1:1 to about 3:1.

114. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 1:1.

115. (previously presented) The method of claim 99, wherein the modafinil compound is modafinil, the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin, and the modafinil compound:cyclodextrin mixture contains 2-hydroxypropyl-β-cyclodextrin and modafinil at a molar ratio of about 1:1.

116. (previously presented) The method of claim 115, wherein the modafinil compound is the levorotatory form of modafinil.

117. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture is orally administered to treat sleepiness, to promote wakefulness, to stimulate appetite, or to stimulate weight gain.

118. (previously presented) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture comprises at least one unit dose of a modafinil compound.

119. (previously presented) The method of claim 118, wherein the unit dose is from about 10 mg to about 400 mg.

120. (previously presented) The method of claim 118, wherein the unit dose is 100 mg or 200 mg.

121. (previously presented) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 10% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

122. (previously presented) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 25% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

123. (previously presented) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 50% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

124. (previously presented) The method of claims 121, 122, or 123 wherein the increase in the blood serum level is within the first hour of oral administration to the mammal.

125. (previously presented) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides substantially the blood serum profile of FIG. 1.

126. (currently amended) A method of delivering modafinil to the bloodstream of a mammal comprising the step of orally administering to the mammal ~~a therapeutically effective amount of~~ a modafinil compound:cyclodextrin mixture, wherein the mixture provides an aqueous solubility of the modafinil compound of at least about 30 mg/mL.

127. (previously presented) The method of claim 126, wherein the modafinil compound is modafinil.

128. (previously presented) The method of claim 127, wherein the modafinil compound is the levorotatory form of modafinil.

129. (previously presented) The method of claim 126, wherein the cyclodextrin is selected from the group consisting of β-cyclodextrin, a hydroxypropyl-β-cyclodextrin and β-cyclodextrin

sulfobutyl ether.

130. (canceled)

131. (previously presented) The method of claim 126, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 1:1.

132. (previously presented) The method of claim 126, wherein the modafinil compound:cyclodextrin mixture comprises at least one unit dose of a modafinil compound.

133. (previously presented) The method of claim 132, wherein the unit dose is 100 mg or 200 mg.

134. (previously presented) The method of claim 126, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 10% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

135. (new) The method of claim 99, wherein the cyclodextrin masks the taste of the modafinil compound.

136. (new) The method of claim 126, wherein the cyclodextrin masks the taste of the modafinil compound.